DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3761. Misbranding of sulfathiazole tablets. U. S. v. Hugh Allen (Hugh Allen, Druggist). Plea of guilty. Imposition of sentence suspended and defendant placed on probation for 6 months. (F. D. C. No. 31562. Sample Nos. 3180–L, 3181–L.)

INFORMATION FILED: April 21, 1952, Northern District of West Virginia, against Hugh Allen, trading as Hugh Allen, Druggist, Petersburg, W. Va.

INTERSTATE SHIPMENT: From the State of Indiana into the State of West Virginia of quantities of *sulfathiazole tablets.*

ALLEGED VIOLATION: On or about May 10 and 15, 1951, while a number of tablets of the drug were being held for sale after shipment in interstate commerce, the defendant caused a number of such tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the repackaged drug was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the repackaged drug; and, Sections 502 (f) (1) and (2), the labeling of the repackaged drug failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 15, 1952. A plea of guilty having been entered, the court suspended the imposition of sentence and placed the defendant on probation for 6 months.

3762. Misbranding of Seconal Sodium capsules. U. S. v. Andrew Kolanowski. Plea of guilty. Fine, $100. (F. D. C. No. 32746. Sample No. 9420–L.)

INFORMATION FILED: April 25, 1952, Northern District of Illinois, against Andrew Kolanowski, an assistant pharmacist for Marshall Drugs, Chicago, Ill.

ALLEGED VIOLATION: On or about April 5, 1951, while a number of *Seconal Sodium capsules* were being held for sale at Marshall Drugs, after shipment in interstate commerce, the defendant caused a number of the capsules to be repacked and dispensed without a physician's prescription, which acts resulted in the drug being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged drug failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: June 2, 1952. A plea of guilty having been entered, the court drug failed to bear adequate directions for use.

3763. Misbranding of Seconal Sodium capsules and dextro-amphetamine sulfate tablets. U. S. v. Joseph S. Pencek (Pencek Circle Pharmacy). Plea of guilty. Fine of $300, plus costs. (F. D. C. No. 32749. Sample Nos. 9641–L to 9644–L, incl.)

INFORMATION FILED: March 24, 1952, Northern District of Illinois, against Joseph S. Pencek, trading as Pencek Circle Pharmacy, Elmwood Park, Ill.

ALLEGED VIOLATION: On or about March 15 and 21 and April 3 and 17, 1951, while quantities of *Seconal Sodium capsules* and *dextro-amphetamine sulfate tablets* were being held for sale at the Pencek Circle Pharmacy, after shipment in interstate commerce; the defendant caused a quantity of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: April 25, 1952. A plea of guilty having been entered, the court imposed a fine of $300, plus costs.

3764. Misbranding of dextro-amphetamine sulfate tablets, racemic amphetamine sulfate tablets, Seconal Sodium capsules, and Amytal tablets. U. S. v. Jacob Chubat (Chubat Pharmacy). Plea of guilty. Fine of $300, plus costs. (F. D. C. No. 32747. Sample Nos. 9404–L to 9409–L, incl.)

INFORMATION FILED: March 24, 1952, Northern District of Illinois, against Jacob Chubat, trading as Chubat Pharmacy, Chicago, Ill.

ALLEGED SHIPMENT: On or about March 21, April 3 and 11, and May 5, 10, and 16, 1951, while quantities of *dextro-amphetamine sulfate tablets*, *racemic amphetamine sulfate tablets*, *Seconal Sodium capsules*, and *Amytal tablets* were being held for sale at the Chubat Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.